



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 9 1999 2282 '99 JUN 11 A9:52

The Honorable Richard F. Colburn
Maryland State Senator
409 James Senate Office Building
Annapolis, Maryland 21401-1991

Dear Senator Colburn:

This is in response to Senator Barbara A. Mikulski's letter of May 20, 1999, on your behalf, and that of Wheeler R. Baker of the Maryland House of Delegates and Karen Oertel, owner of W.H. Harris Seafood, Inc. Senator Mikulski has asked us to respond directly to you.

You wrote concerning the petition for a performance standard for *Vibrio vulnificus* in raw shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest. As you may know, FDA published a request for comments on this petition in the Federal Register of January 21, 1999. We have enclosed a copy for your reference.

You state that "This proposal will impose new, costly and unnecessary regulations on the shellfish industry. . . (and) will have a disastrous effect upon the seafood industry. . . (and) upon the entire State of Maryland." We appreciate your comments on the petition and we have entered them into the Administrative Record for this petition. They will be reviewed in the Agency's deliberations on this petition.

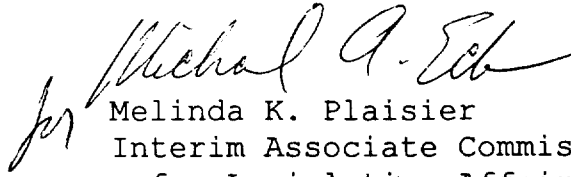
98P-0504

C257/ANS

Page 2 - The Honorable Richard F. Colburn

We trust this information responds to your concerns. Please contact us if we may be of further assistance in this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Melinda K. Plaisier".

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosure

cc: Docket Management (Docket No 98P-0504)

The Honorable Barbara A. Mikulski
United States Senate
Washington, D.C. 20510-2003

BARBARA A. MIKULSKI
MARYLAND

SUITE 709
HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510

(202) 224-4654
TDD: (202) 224-5223

United States Senate
WASHINGTON, DC 20510-2003

May 20, 1999

Ms. Diane Thompson
Assoc. Commissioner for Legislative Affs.
Dept. of Health & Human Services
Food and Drug Administration
5600 Fishers Ln., 1555 Parklawn Bldg.
Rockville, Maryland 20857

Dear Diane:

I am writing to request your consideration of the attached correspondence from Maryland State Senator Richard F. Colburn. Please respond directly to Mr. Colburn and send a copy to Emily Gilbert of my staff. If you have any questions, please call Ms. Gilbert at (202) 224-4654.

Thank you for your assistance.

Sincerely,



Barbara A. Mikulski
United States Senator

BAM:efg
Enclosure

No. 99- 3674

SUITE 253
WORLD TRADE CENTER
BALTIMORE, MD 21202-3041
(410) 962-4510

SUITE 202
60 WEST STREET
ANNAPOLIS, MD 21401-1933
(410) 263-1805

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(410) 546-7711

World Wide Web Home Page:
<http://mikulski.senate.gov/>

E-Mail Address:
senator@mikulski.senate.gov

RICHARD F. COLBURN

STATE SENATOR

37th Legislative District

Caroline County
Dorchester County
Talbot County
Wicomico County

Member

Judicial Proceedings Committee
Joint Committee on Administrative,
Executive and Legislative Review
Executive Nominations Committee
Special Joint Oversight Committee on
Chesapeake Bay Critical Areas



THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401-1991

April 27, 1999

IN REPLY PLEASE REFER TO OFFICE INDICATED

☐ *Annapolis Office*

409 James Senate Office Building
Annapolis, Maryland 21401-1991
410-841-3590
1-800-492-7122 Ext. 3590

☐ *Mid-Shore Office*

P.O. Box 1237
Cambridge, Maryland 21613
410-228-1137 · 410-819-3337
Fax 410-376-3737

☐ *Wicomico County Office*

P.O. Box 537
Hebron, Maryland 21830
410-548-3737

U. S. Senator Barbara A. Mikulski
709 Senate Hart Office Building
Washington, D.C. 20510-2003

Dear Senator Mikulski:

I am in receipt of a memorandum and information from a local seafood company regarding the Food and Drug Administration's proposal to ban the consumption of raw oysters or to impose a mandatory post-harvest treatment or pasteurization of fresh oysters intended for raw consumption. This proposal will impose new, costly and unnecessary regulations on the shellfish industry.

As you well know, if allowed, this ban will have a disastrous effect upon the seafood industry, not only on the Eastern Shore, but, upon the entire state of Maryland. The seafood industry is the third largest industry in the state with an annual revenue of more than \$800 million. Please review the enclosed information and assist our efforts in supporting the seafood industry.

Thank you for your cooperation.

Sincerely,

A handwritten signature in dark ink, appearing to read "R. Colburn", written in a cursive style.

Richard F. Colburn

Enclosure

WHEELER R. BAKER
36th Legislative District
Caroline, Cecil, Kent, Talbot
and Queen Anne's Counties

Appropriations Committee



Annapolis Office
422 Lowe House Office Building
Annapolis, Maryland 21401-1991
410-841-3189
1-800-492-7122 Ext 3189
E-Mail wheeler_baker@house.state.md.us

District Office
918 Chester River Drive
Grasonville, Maryland 21638-9801
410-758-3960
Fax 410-827-9688
E-Mail wheeler@dmv.com

The Maryland House of Delegates
ANNAPOLIS, MARYLAND 21401-1991

MEMORANDUM

April 20, 1999

TO: Members of the Eastern Shore Delegation
FROM: Wheeler R. Baker
RE: FDA Regulations - Consumption of Raw Oysters

I am forwarding a copy of a memo and backup information I have received from Karen Oertel, owner of W. H. Harris Seafood, Inc. After reviewing the materials Karen has sent, it appears the FDA is considering banning the consumption of raw oysters.

I would appreciate your thoughts on how we should proceed.

/vcs
Enclosure

OVERSEAS CLAMS STEAMED CRABS EAST CLAMS BAYMORE BRAND

W. H. HARRIS SEAFOOD, Inc.

202 PHONE 227-6164
PORT HARBOR

POST OFFICE BOX 143, CHESTER, MARYLAND 21619

TAX PHONE 761-437-4357
CHESTER, MD

DATE: 4-16-99
TO: Delegate Wheeler Baller
FROM: Karen Harris Ostel
NUMBER OF PAGES INCLUDING COVER SHEET: 14
MESSAGE: Please Review this information pertaining to the an issue on FDA Regulations on the consumption of raw oysters. The FDA is being petitioned by a group to stop the public from eating raw molluscan shellfish. I have attached several pieces of information that will inform you of the issue. The FDA is taking comment on the issue until April 21st. This issue is pressing and of grave concern to our industry. Please call if you have questions. I hope you will consider making comment to the FDA supporting consumer choice. There is a Draft Resolution that has been drawn up for public officials.

RICHARD F. COLBURN
STATE SENATOR

37th Legislative District
Caroline County
Dorchester County
Talbot County
Wicomico County

Member

Judicial Proceedings Committee
Joint Committee on Administrative,
Executive and Legislative Review
Executive Nominations Committee
Special Joint Oversight Committee on
Chesapeake Bay Critical Areas



THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401-1991

April 27, 1999

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☐ *Annapolis Office*
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410-228-1137 · 410-819-3337
Fax 410-376-3737

☐ *Wicomico County Office*
P.O. Box 537
Hebron, Maryland 21830
410-548-3737

Congressman Wayne T. Gilchrest
2245 Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Congressman Gilchrest:

I am in receipt of a memorandum and information from a local seafood company regarding the Food and Drug Administration's proposal to ban the consumption of raw oysters or to impose a mandatory post-harvest treatment or pasteurization of fresh oysters intended for raw consumption. This proposal will impose new, costly and unnecessary regulations on the shellfish industry.

As you well know, if allowed, this ban will have a disastrous effect upon the seafood industry, not only on the Eastern Shore, but, upon the entire state of Maryland. The seafood industry is the third largest industry in the state with an annual revenue of more than \$800 million. Please review the enclosed information and assist our efforts in supporting the seafood industry.

Thank you for your cooperation.

Sincerely,

Richard F. Colburn

Enclosure

OYSTERS • CLAMS • STEAMED CRABS • SOFT CLAMS • BAYSIDE BRAND

W. H. HARRIS SEAFOOD, Inc.

BUS. PHONE EXTENSION
22 W. HARRIS

POST OFFICE BOX 143, CHESTER, MARYLAND 21619

FAX PHONE 801-827-8999
CHESTER, MD

April 16, 1999

From: Karen Oertel, Officer of W. H. Harris Seafood

MEMO: Delegate Wheeler Baker

Reference: Petition by CSPI (Center for Science in the Public Interest) petition to FDA to establish a performance standard for Vibrios in molluscan shellfish.

I wanted to make you aware of a situation that could be facing the Maryland Seafood Industry. The special interest group CSPI has petitioned the FDA to stop the consumption of raw shellfish in the Southern States. Our immediate concern is that this state will also become a part of their strategy. The FDA has always linked the seafood industry together in the past. I do not believe this issue will be any different. The impact to the seafood industry could be devastating. The FDA is accepting comments until April 21, 1999.

We believe that the consumer education and awareness campaign about the at risk category which is those persons who could be susceptible to illness from Vibrio due to a pre-existing condition, has been effective in greatly reducing serious illnesses and deaths. The ISSC, MSI and the NFI will continue to support this education to the public but also believes as we do that the consumer has the right to make a choice to consume a raw molluscan product.

For your review I have attached information concerning the problem, our letter to the FDA and suggested material to be used. The draft resolution is being suggested for use by legislators, commissioners, and other influential individuals. The petition is for the citizens to have an opportunity to support the American concept of consumer choice.

I hope you can consider giving your support to the seafood industry concerning this issue.

- Items attached:
1. W. H. Harris Seafood Inc. letter to FDA.
 2. MSI letter to it's membership supporting consumer choice.
 3. Letter from Gulf Oyster Industry Task Force.
 4. Suggested Draft Resolution of legislators, commissioners, Governors etc.
 5. Petition for Coalition for Consumer Choice

risk. Supporters of these proposed rules will admit that as few as only 15 to 20 people per year out of a total at risk population of 30 million are suspected at risk when consuming a raw oyster product. Currently there is insufficient data supporting a specific level and a link between V.v. levels and illness and death. The ISSC and most State Public Health bodies believe that consumer education is an intelligent, measured and appropriate response to health concerns and fully support continuing both the education campaigns and ISSC authority on the issue. We do not need a performance standard established for either V.v. or V.p. and we will oppose the establishment of a performance standard for Vibrio Bacteria.

We are also involved in a large seafood restaurant and the public desires and demands a raw oyster product. Sales of the raw oyster have been high. I believe that if this pasteurized product is made mandatory, sales of the oyster will plummet. The pasteurized product is of poor taste and poor quality and for a real oyster eater will not be considered as tasty.

Consumer choice is an important part of our heritage here in America and I believe the consumer has the right to choose an oyster product that they have enjoyed for over 150 years raw-mucous and delicious. I urge the FDA to reject a mandatory post-harvest treatment requirement for all oysters. It is unnecessary and deprives the public of consumer choices.

Sincerely,

Wm. Jerry Harris

Wm. Jerry Harris
president

OYSTERS

CLAMS

STEAMED CLAMS

SOFT CLAMS

BAYSHORE BRAND

W. H. HARRIS SEAFOOD, Inc.

BUS. PHONE 801-8104
HENT MARSH

POST OFFICE BOX 145, CHESTER, MARYLAND 21619

FAX PHONE 801-821-8019
CHESTER MD

April 9, 1999

#1
Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Reference - Post Harvest Treatment of Molluscan Shellfish.

The Molluscan Shellfish has long been a product of the United States and other countries and has been harvested for consumption by the public for at least 150 years. The oyster is consumed in various manners, but has always been desired as a Raw Bar product and enjoyed by the public on the half shell, raw.

Recently it has come to my attention that there are efforts by a special interest group, the Center for Science in the Public Interest (CSPI) to encourage a mandatory post-harvest treatment or pasteurization of fresh oysters intended for raw consumption. A regulation of this nature will impose new, costly and unnecessary regulations on the shellfish industry in general. More importantly, it will also take away the consumers choice between the regularly consumed fresh oyster and forcing the consumer to eat the treated product which totally changes the quality, taste and texture of the oyster.

Our firm W.H. Harris Seafood has been in the processing industry for 52 years. We offer the public a safe, delicious and natural Raw Bar product. As a participant in this industry, we have worked closely with the States, (ISSC) Interstate Shellfish Sanitation Conference, the (MSI) Molluscan Shellfish Institute, the (NFI) National Fisheries Institute and the (FDA) U.S. Food and Drug Administration in developing and initiating a campaign of consumer education and awareness about the "at risk" category which could be susceptible to illness from (V.v.) *V. Vulnificus* and (V.p.) *Vibrio Parahaemolyticus* from shellfish. Results have been excellent and have greatly reduced serious illnesses and deaths by alerting those with pre-existing conditions of possible